



**PATENT**

**CERTIFICATE OF MAILING**

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Jane A. Walker

January 20, 2006  
Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Peyman  
Serial No.: 10/667,161  
Filed: September 19, 2003  
Group Art Unit: 1615  
Confirmation No.: 8452  
Examiner: Sheikh  
Title: **OCULAR SOLUTIONS**  
Attorney Ref.: PMAN-25

Cincinnati, Ohio 45202

January 20, 2006

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

In accordance with the duty of candor and good faith imposed by 37 C.F.R. §1.56 and means of complying therewith according to 37 C.F.R. §§1.97 and 1.98, the references listed on the attached form PTO-1449 are called to the attention of the United States Patent and Trademark Office in connection with the above-identified patent application.

01/25/2006 RMEBRAFT 00000063 233000 10667161  
01 FC:1806 180.00 DA

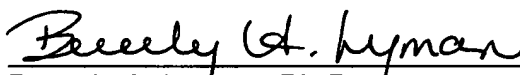
Applicant has the following co-pending applications disclosing use of one or more macrolides: 10/289,772, 10/631,143, and 10/752,124. The references submitted in this IDS are or were submitted or cited in applicant's co-pending applications, and are included in the pending application to ensure compliance with applicant's duty of disclosure under 37 C.F.R. §1.97.

The Examiner is urged to consider the cited references listed on the attached form PTO-1449, and to make an independent decision with respect to materiality.

In accordance with 37 C.F.R. §1.97(c), attached is a check in the amount of \$180.00 as set forth in 37 C.F.R. §1.17(p). If any additional fee is required to complete this communication, please charge Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

  
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The PTO did not receive the following  
listed item(s) the check.

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. PMAN/25		SERIAL NO. 10/667,161	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)				APPLICANT Gholam Peyman		FILING DATE September 19, 2003	
				GROUP 1615			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A.A	4 0 7 9 0 3 8	03/14/78	Choi et al	260	47	03/05/76
	A.B	4 0 9 3 7 0 9	06/06/78	Choi et al	424	19	01/28/75
	A.C	4 1 3 1 6 4 8	12/26/78	Choi et al	424	22	03/02/78
	A.D	4 1 3 8 3 4 4	02/06/79	Choi et al	252	1	08/24/77
	A.E	4 1 8 0 6 4 6	12/25/79	Choi et al	528	153	03/03/78
	A.F	4 3 0 4 7 6 7	12/08/81	Heller et al	424	78	05/15/80
	A.G	4 9 4 6 9 3 1	08/07/90	Heller et al	528	320	06/14/89
	A.H	5 4 2 9 4 6 0	03/15/94	Nussenblatt et al	514	11	12/20/89
	A.I	5 3 8 7 5 8 9	02/07/95	Kulkarni	514	291	11/17/92
	A.J	5 4 1 1 9 6 2	05/1995	Kaswan			
	A.K	5 4 5 7 1 8 2	10/10/95	Wiederrecht et al	530	402	02/15/94
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS							
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	A.L	WO 00/66122	11/09/00	PCT	A61K	31/436	N/A
	A.M	WO 02/085928	10/31/02	PCT	C07K	7/54	Abstract only
	A.N	WO 2004/014373	02/19/04	PCT	A61K	31/436	N/A
	A.O	EP 1074255	02/07/01	EP	A61K	31/40	N/A
	A.P	WO 99/34830	07/15/99	PCT	A61K	47/18	N/A
	A.Q	AU 17386/88	Unknown	AU		Unknown	N/A
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	A.R	Algvere et al, <u>Long-term outcome of RPE allografts in non-immunosuppressed patients with AMD</u> , European J of Ophthalmology (1999), 9(3):217-230					
	A.S	Anderson et al., <u>A Role for Local Inflammation in the Formation of Drusen in the Aging Eye</u> , American Journal of Ophthalmology, Vol. 134, No. 3, September 2002, pp. 411-431					
	A.T	Apel et al., <u>A subconjunctival degradable implant for cyclosporine delivery in corneal transplant therapy</u> , Curr. Eye Res. 14:659-667, 1995					
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if citation considered, whether or not in conformance. Draw line through citation only if not in conformance <u>and</u> not considered. Include a copy of this form with next communication to applicant.							

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	B.A	5	7	7	0	6	0	7	06/23/98	Honbo et al	514	302	07/18/94
	B.B	5	7	7	3	0	1	9	06/30/98	Ashton et al	424	423	09/27/95
	B.C	5	9	5	2	3	7	1	09/14/99	Baker et al	514	443	10/08/97
	B.D	5	9	6	8	5	4	3	10/19/99	Heller et al	424	425	12/05/97
	B.E	6	0	0	4	5	6	5	12/21/99	Chiba	424	278.1	09/23/97
	B.F	6	3	3	1	3	1	3	12/2001	Wong et al			
	B.G	6	3	5	0	4	4	2	02/26/02	Garst	424	78.04	05/30/2001
	B.H	6	4	6	2	0	7	1	10/2002	Castillejos			
	B.I	6	4	8	2	7	9	9	11/2002	Tuse et al			
	B.J	6	5	0	6	2	0	6	07/22/03	Nelson et al	424	426	08/04/00
	B.K	6	5	3	4	6	9	3	03/18/03	Fischell et al.	A61F	13/00	01/31/01
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		DOCUMENT NUMBER						PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)	
	B.L	AU 20350/92						Unknown	AU		Unknown	N/A	
	B.M	CN 1333018						01/30/02	CN	A61K	9/06	Abstract only	
	B.N	CN 1340358						03/20/02	CN	A61K	38/13	Abstract only	
	B.O	CN 1456350						11/19/03	CN	A61K	9/00	Abstract only	
	B.P	DE 19810655						09/16/99	DE	A61K	38/13	Abstract only	
	B.Q	EP 1142566						10/10/01	EP	A61K	9/08	Abstract only	
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)													
	B.R	Aramant et al, <u>Retinal transplantation</u> , Science & Medicines (2000), 7:20-29											
	B.S	Carmo et al, <u>Effect of cyclosporin A on the blood-retinal barrier permeability in streptozotocin-induced diabetes</u> , Mediators of Inflammation (2000), 9(5):243-248											
	B.T	Chiou, <u>Topical Treatment of Ocular Hypertension, Glaucoma, Ischemic Retinopathy and Age-Related Macular Degeneration with Ophthalmic Formulation of Dopamine Antagonists</u> , U.S. Patent Application Publication No. US 203/0069232, published 04/10/03											
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	C.A	6	6	1	3	3	5	5	09/02/03	Ng et al	424	462	05/11/01
	C.B	6	6	1	7	3	4	5	09/09/03	Gregory et al	514	395	09/12/00
	C.C	6	6	6	7	3	7	1	12/23/03	Ng et al	525	462	11/14/02
	C.D	6	6	7	0	3	9	8	12/2003	Edwards et al			
	C.E	6	6	7	3	8	0	7	01/2004	Sakai et al			
	C.F	6	7	1	3	0	8	1	03/2004	Robinson et al			
	C.G												
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	C.I												
	C.J												
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## FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

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	C.L	JP 10-218787	08/18/98	JP	A61K	38/22	Yes
	C.M	JP 1997030966	02/04/97	JP	A61K	31/365	Yes
	C.N	JP 2001-064198	03/13/01	JP	A61K	38/22	Yes
	C.O	WO 02/24234	03/28/02	PCT	A61K	48/00	N/A
	C.P	WO 03/051385	06/26/03	PCT	A61K	38/13	Abstract only
	C.Q	WO 03/017990	03/06/03	PCT	A61K	31/00	N/A

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	C.R	Cicciarelli et al, <u>Pharmacokinetics of subconjunctivally administered cyclosporine A. Local delivery prior to chemotherapy for retinoblastoma</u> , IOVS (3/15/2001), 42(4):S332
	C.S	Costantini LC, et al., <u>Immuophilin Ligands and GDNF Enhance Neurite Branching or Elongation from Developing Dopamine Neurons in Culture</u> , Experimental Neurology 164,60-60 (2000)
	C.T	Das et al, <u>The transplantation of human fetal neuroretinal cells in advanced retinitis pigmentosa patients: Results of a long-term safety study</u> , Experimental Neurology (1999), 157:58-68

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	D.L	WO 2004/096261	11/11/04	PCT	A61K	38/13	Abstract only
	D.M	WO 2004/043480	05/27/04	PCT	A61K	38/00	N/A
	D.N	WO 2005/030205	04/07/05	PCT	A61K	31/436	N/A
	D.O	WO 2005/011813	02/10/05	PCT	A61P	27/02	N/A
	D.P	WO 89/01772	03/09/89	PCT	A61K	9/00	N/A
	D.Q	WO 99/42104	08/26/99	PCT	A61K	31/435	N/A
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	D.R	Del Cerro et al, <u>Histologic correlation of human neural retinal transplantation</u> , Invest. Ophthalmology & Visual Science (2000), 41(10):3142-3148					
	D.S	Donnenfeld et al., <u>Cyclosporine provides effective treatment for dry eye</u> , Therapeutic Updates in Ophthalmology, Special Issue, July 1999, pp. 1-3					
	D.T	Enyedi et al, <u>Pharmacokinetics and toxicity of an intravitreal device providing sustained release of cyclosporine (CsA) and dexamethasone (DEX)</u> , Invest. Ophthalmology and Visual Science, Vol. 35, No. 4, 1994, p. 1906, and Annual Meeting of the Association for Research in Vision and Ophthalmology, Sarasota, FL, USA, May 1-6, 1994, abstract					
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	E.R	Enyedi et al, <u>An intravitreal device providin sustained release of cyclosporine and dexamethasone</u> , Curr. Eye Res. May 1996, Vol. 15, No. 5, pp. 549-557					
	E.S	Garweg et al, <u>Therapy of Goldmann-Favre's Vitreo-Retinal Degeneration with Cyclosporin A and Bromocriptine</u> , Klinische Monatsblatter fur Augenheilkunde, Vol., 199, No. 3, September 1991, pp. 199-205					
	E.T	Gilbard, <u>EW Interview: Electrolyte balance is key to dry-eye product's success</u> , EyeWorld, February 2000, pp. 20ff					
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(37 CFR 1.98(b))		FILING DATE September 19, 2003	GROUP 1615

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F.L					
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F.O					
F.P					
F.Q					

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

F.R	Grisolano et al., <u>Retinal Toxicity Study of Intravitreal Cyclosporin</u> , Ophthalmic Surgery, March 1986, 17:155-156
F.S	Hageman et al., <u>Diagnostics and Therapeutics for Macular Degeneration-Related Disorders</u> , U.S. Patent Application Publication No. US 2002/0015957, published 02/07/02
F.T	Jiang et al, <u>Corneal electroretinographic function rescued by normal retinal pigment epithelial grafts in retinal degenerative Royal College of Surgeons rats</u> , Invest. Ophthalmology & Visual Science (1994), 35(13):4300-4308

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	G.R	Karacorlu et al., <u>Lack of toxicity of intravitreally administered interferon Alpha-2a</u> , Ophthalmic Surger (1999), 23:833-35					
	G.S	Keep et al., <u>Introduction: Immunosuppressants as Neuroprotective Agents" Immunosuppressant Analogs in Neuroprotection, Part I: Immunosuppressants, Neurologic Disorders, and Neuroprotection</u> , Ed: Borlongan & Sanberg, Humana Press Inc., Totowa, NJ, pp.3-32					
	G.T	Kiryu et al., <u>In Vivo Evaluation of the Inhibitory Effects of Tacrolimus (FK506) on Leukocyte Accumulation During Retinal Ischemia Reperfusion Injury</u> , Poster Presentation 1247-B128					
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H.P					
H.Q					

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

H.R	Lai et al, <u>Local immunosuppression prolongs survival of RPE xenografts labeled by retroviral gene transfer</u> , IOVS (9/2000), 41(10):3134-3141
H.S	Lallemant et al., <u>Cyclosporine A delivery to the eye: A pharmaceutical challenge</u> , European Journal of Pharmaceutics and Biopharmaceutics, 45 (2003), pp. 307-318
H.T	Lipner, <u>Dry Eye 101: Developing etiologies and treatments fort his widespread syndrome</u> , EyeWorld, February 1999, pp. 19ff

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## OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

I.R	Lipper et al., <u>Recent therapeutic advances in dermatology</u> , JAMA, Vol. 283, No. 2, January 12, 2000, pp. 175-177
I.S	Lopez et al, <u>Transplanted retinal pigment epithelium modifies the retinal degeneration in the RCS</u> , Invest. Ophthalmology & Visual Science (1989). 30:586-588
I.T	Lund et al, <u>Subretinal transplantation of genetically modified human cell lines attenuates loss of visual function in dystrophic rats</u> , PNCS (2001), 98(17):9942-9947

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J.R	Martin DF et al., <u>Synergistic Effect of Rapamycin and Cyclosporin A in the Treatment of Experimental Autoimmune Uveoretinitis</u> , The Journal of Immunology, 1995, 154:922-927
J.S	Nicoletti et al, <u>The effects of deoxyspergualin on the development of diabetes in diabetes-prone BB rats</u> , Scandinavian Journal of Immunology (1992), 36(3):415-420
J.T	Passos et al, <u>Ocular Toxicity of Intravitreal Tacrolimus</u> , phthalmic Surgery and Lasers, March/April 2002, Vol. 33, No. 2, pp.140-144

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)				APPLICANT Gholam Peyman			
				FILING DATE September 19, 2003		GROUP 1615	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	K.L						
	K.M						
	K.N						
	K.O						
	K.P						
	K.Q						
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	K.R	PCT, <u>International Search Report</u> , PCT/2004/024054, mailed 07/27/04, 7 pg.					
	K.S	PCT, <u>International Search Report</u> , PCT/US03/28315, mailed 06/15/04, 6 pages					
	K.T	Peyman et al, <u>Keratitis (Noninfectious)</u> , Principles and Practice of Ophthalmology, W.B. Saunders Company, 1980, pp.446-449					
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	L.R	Peyman, <u>Ocular Solutions</u> , U.S. Application Publication No. 2005/0063997, published 03/24/05, Serial No. 10/752,124, filed 01/06/04					
	L.S	Peyman et al., <u>Intravitreal Surgery: Principles and Practice, 2nd Edition</u> , 1994, Apleton & Lange, CT, pp. 443-452					
	L.T	Peyman et al., <u>Implantation of a sustained-release ganciclovir implant</u> , Vitreoretinal Surgical Techniques, Martin Dunitz Ltd., 2001, Chapter 45, pp. 521-531					
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(37 CFR 1.98(b))							

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

M.R	Peyman, <u>Treatment of Ocular Disease</u> , U.S. Application Publication No. 2005/0025810, published 02/03/05, Serial No. 10/631,143, filed 07/31/03
M.S	Peyman et al., <u>Intravitreal drug therapy</u> , Japanese Journal of Ophthalmology (1989, 33(4):392-404
M.T	Peyman, <u>Treatment of Ocular Disease</u> , U.S. Application Publication No. 2004/0092435, published 05/13/04, Serial No. 10/289,772, filed 11/07/02

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	N.R	Peyman, <u>Ocular Solutions</u> , U.S. Application Publication No. 2005/0063996, published 03/24/05, Serial No. 10/667,161, filed 09/19/03					
	N.S	Revill et al., <u>Genetically Engineered Analogs of Ascomycin for Nerve Regeneration</u> , Journal of Pharmacology and Experimental Therapeutics, Vol. 302:1278-1285 (2002)					
	N.T	Shen et al, <u>Combined effect of cyclosporine and sirolimus on improving the longevity of recombinant adenovirus-mediated transgene expression in the retina</u> , Archives of Ophthalmology (7/2001), 119(7):1033-1043					
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	O.R	Stosic-Grujicic et al, <u>Leflunomide protects mice from multiple low dose streptozotocin (MLD-SA)-induced insulinitis and diabetes</u> , Clinical & Experimental Immunology (1999), 117(1):44-50					
	O.S	Ueno, <u>Use of Macrolide Compounds for the Treatment of Dry Eye</u> , U.S. Patent Application Publication 20030130301, published 07/10/03, Serial No. 10/354,083, filed 01/30/03					
	O.T	Wakelee-Lynch, <u>Interferon may offer first drug therapy for diabetic retinopathy</u> , Diabetes Care (1992), 15(2):300-301					
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